UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

NOVO NORDISK A/S AND NOVO NORDISK INC., Plaintiffs, v. DRIP DROP HYDRATION STATION LLC D/B/A BEDSIDE MANNER TELEHEALTH, Defendant.	Case No. 1:24-cv-00640

COMPLAINT

Plaintiffs Novo Nordisk A/S ("NNAS") and Novo Nordisk Inc. ("NNI") (collectively, "Plaintiffs" or "Novo Nordisk") file their complaint against Drip Drop Hydration Station LLC d/b/a Bedside Manner Telehealth ("Defendant") for trademark infringement, false advertising and unfair and deceptive trade practices, and seek injunctive and other relief. Plaintiffs allege as follows, on actual knowledge with respect to themselves and their own acts, and on information and belief as to all other matters.

INTRODUCTION

1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases like diabetes and obesity.

2. The development of semaglutide is an example of Novo Nordisk's commitment to innovation for people living with chronic diseases. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's three prescription-only medicines approved by the Food and Drug Administration ("FDA"): Ozempic® (semaglutide) injection and Rybelsus®

(semaglutide) tablets for adults with type 2 diabetes and Wegovy® (semaglutide) injection for chronic weight management.

3. Novo Nordisk is the only company in the United States with FDA-approved medicines containing semaglutide.

4. Novo Nordisk is also the only company authorized to identify its FDA-approved semaglutide medicines using the trademarks Ozempic®, Wegovy®, and Rybelsus®.

5. The FDA has not approved any generic versions of semaglutide medicines. To the contrary, the FDA has sent warning letters to companies that claimed that their Unapproved Products have the "same active ingredient as Ozempic, Rybelsus, and Wegovy," noting that Ozempic and Wegovy are currently the only "two injectable semaglutide products FDA-approved for the U.S. market."[1]

6. This is an action brought pursuant to the Lanham Act, 15 U.S.C. §§ 1051 et seq., related state laws, and the common law arising out of Defendant's infringement of Plaintiffs' rights in their Wegovy® mark and Defendant's acts of false advertising and unfair competition.

7. Defendant uses Novo Nordisk's Wegovy® mark to market and sell to patients compounded drug products that purport to contain semaglutide.

8. Even though such compounded drug products having not been evaluated by the FDA for their safety, effectiveness, or quality, Defendant falsely and misleadingly represents to patients that its products are FDA-approved or the same as, or equivalent to, Novo Nordisk's FDA-approved semaglutide medicines.

[1]FDA – Warning Letter to Ozempen.com, MARCS-CMS 684435 — JUNE 24, 2024 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozempencom-684435-06242024 (last updated July 2, 2024).

9. Defendant's conduct is likely to confuse and deceive patients into mistakenly believing that they are purchasing authentic Novo Nordisk medicines or medicines that have been evaluated by the FDA, studied in clinical trials, and deemed safe and effective.

THE PARTIES

10. Plaintiff NNAS is a corporation organized and existing under the laws of the Kingdom of Denmark and has its principal place of business in Bagsværd, Denmark.

11. Novo Nordisk developed the Ozempic®, Wegovy®, and Rybelsus® medicines.

12. NNI is a corporation organized and existing under the laws of Delaware and has its principal place of business in Plainsboro, New Jersey.

13. NNAS has granted to NNI exclusive rights to market, advertise, promote, offer for sale and sell Ozempic® and Wegovy® medicines in the United States.

14. NNI promotes, offers, and/or sells Novo Nordisk's Ozempic® and Wegovy® medicine throughout the United States, including in this District.

15. Defendant Drip Drop Hydration Station LLC d/b/a Bedside Manner Telehealth is an Ohio limited liability company with a registered business address at 120 Julep Lane, Cincinnati, Ohio 45218, in this judicial district.

16. Defendant sells and promotes compounded drug products that purport to contain semaglutide and that are not approved by the FDA ("Unapproved Compounded Drugs").

17. Defendant falsely claims, or otherwise misleadingly suggests, that its Unapproved Compounded Drugs are the same as or equivalent to Ozempic®, and Wegovy® medicines.

JURISDICTION AND VENUE

18. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 35 U.S.C. § 1121 and 28 U.S.C. § 1338(a).

19. The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. § 1338(b).

20. Defendant is subject to personal jurisdiction in this District because Defendant is an Ohio limited liability company and has a principal place of business in Ohio.

21. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates in this District, manufactures and/or sells its compounded drug products that purport to contain semaglutide in this District, and otherwise conducts business in this District.

NOVO NORDISK'S FDA-APPROVED SEMAGLUTIDE MEDICINES AND OZEMPIC® AND WEGOVY®, AND RYBELSUS® TRADEMARKS

22. Plaintiffs use the trademarks "Ozempic," "Wegovy," and "Rybelsus" to identify and promote the FDA-approved Ozempic®, Wegovy®, and Rybelsus® medicines. The Ozempic®, Wegovy®, and Rybelsus® medicines are sold and marketed in the United States by NNAS's indirect, wholly-owned subsidiary, NNI.

23. The Ozempic® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise. The Ozempic® medicine also lowers the risk of major cardiovascular events such as stroke, heart attack, or death in adults with type 2 diabetes and known heart disease.

24. The Wegovy® medicine is indicated to reduce excess body weight and maintain weight reduction long term in adults and children aged ≥ 12 years with obesity, and some adults with overweight and weight-related medical problems, along with a reduced calorie diet and increased physical activity.

25. The Wegovy® medicine is also indicated, with a reduced calorie diet and increased physical activity, to reduce the risk of major adverse cardiovascular events such as

"cardiovascular" death, heart attack, or stroke in adults with known heart disease and with either obesity or overweight.

26. The Rybelsus® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise.

27. The Ozempic®, Wegovy®, and Rybelsus® medicines have been extensively studied in clinical trials and are FDA-approved.

28. Each of the Ozempic®, Wegovy®, and Rybelsus® medicines have a unique safety and efficacy profile which is set forth in its respective product label.

29. The Ozempic®, Wegovy®, and Rybelsus® medicines are prescription-only medicines that should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

30. Novo Nordisk first adopted and used the Wegovy® mark at least as early as 2021, and has used it continuously since that time.

31. The Wegovy® trademark is inherently distinctive.

32. Novo Nordisk has promoted, advertised, and marketed its prescription-only medicine using the Wegovy® mark in many different channels, directed to physicians, other health care professionals, and patients, including on the websites wegovy.com and novonordisk-us.com. As a result of its use of the Wegovy® mark, NNAS owns valuable common law rights in and to the Wegovy® mark.

33. Plaintiff NNAS is the owner of (a) U.S. trademark registration number 6,585,492, issued on December 14, 2021, for the mark Wegovy® for pharmaceutical preparations, in International Class 5; and (b) U.S. trademark registration number 6,763,029, issued on June 21, 2022, for the mark Wegovy® in a stylized form for pharmaceutical preparations, in International

Class 5. True and correct copies of Plaintiff's registrations numbers 6,585,492 and 6,763,029 for the Wegovy® mark are attached hereto as **Exhibit A** and **Exhibit B**, respectively.

34. As a result of Novo Nordisk's long use, promotion, and advertising of the Ozempic®, Wegovy®, and Rybelsus® trademarks and medicines, the Ozempic®, Wegovy®, and Rybelsus® marks are exclusively associated with Plaintiffs, serve to identify genuine Novo Nordisk medicines, and are valuable assets of Novo Nordisk.

35. As a result of Novo Nordisk's long use, promotion, and advertising of the Ozempic®, Wegovy®, and Rybelsus® trademarks and medicines, the Ozempic®, Wegovy®, and Rybelsus® trademarks are well-known, strong, and famous marks, and became such prior to any of the acts of Defendant complained of herein.

DEFENDANT'S SALE OF UNAPPROVED COMPOUNDED DRUGS

36. Novo Nordisk does not sell its FDA-approved semaglutide medicines, Ozempic® and Wegovy®, to Defendant for resale or redistribution.

37. Defendant markets and sells to patients Unapproved Compounded Drugs that purport to contain semaglutide.

38. The FDA has not approved Defendant's Unapproved Compounded Drugs.

39. On information and belief, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them either directly to patients or to Defendant for administration or dispensing to patients.

40. The FDA defines compounding as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a

licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[2]

41. According to the FDA, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients."[3]

42. The FDA has further stated that compounded drugs "do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks."[4]

43. As the FDA has explained, "[c]ompounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness. Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug."[5]

44. The process used to produce most "semaglutide" used in compounding is fundamentally different from the process used to produce the semaglutide in Novo Nordisk's FDA-approved medicines. Novo Nordisk manufactures the semaglutide in its medicines, pursuant to its FDA approval, in yeast cells under a closely controlled multistep process that uses recombinant DNA technology. Most compounded "semaglutide," however, uses a "semaglutide"

[2]Human Drug Compounding, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (last updated Oct. 8, 2024).

[3]Compounding Laws and Policies, https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies (last updated Sept. 10, 2020).

[4]Compounding and the FDA: Questions and Answers, https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (last updated Aug. 5, 2024).

[5]FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded?utm_medium=email&utm_source=govdelivery (last updated July 26, 2024).

manufactured via chemical synthesis. The fundamental differences between these processes have resulted in new impurities, higher levels of known impurities, immunogenicity concerns, and potential stability issues in tested samples of compounded "semaglutide."[6]

45. The FDA has received reports of adverse events, some requiring hospitalization, related to overdoses from dosing errors associated with compounded "semaglutide" products.[7] Based on data as of September 30, 2024, the FDA's Adverse Event Reporting System (FAERS) database includes 619 cases of adverse events associated with compounded "semaglutide"—nearly triple the number of adverse events for *all* compounded drugs in 2022.[8] Of those 619 cases, the FDA classified 446 as "serious" adverse events, 144 as requiring hospitalization, and twelve as involving deaths. In several instances, patients mistakenly administered five to 20 times more than the intended dose of compounded "semaglutide."

46. The FDA has stated that the containers and packaging (including multidose vials and prefilled syringes) used by compounders, the varying product concentrations, and the instructions accompanying the compounded drug contribute to the potential medical errors.

47. A publication from the Journal of the American Pharmacists Association also highlighted errors where patients accidentally self-administered doses of compounded "semaglutide" up to ten times greater than the intended amount.[9]

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[6]Morten Hach *et al*, Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs, Pharm. Res., (Oct. 8, 2024), *available at* https://pubmed.ncbi.nlm.nih.gov/39379664/.

[7]FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded (last updated July 26, 2024).

[8]FDA Adverse Event Reporting System (FAERS) Public Dashboard, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard (last updated December 7, 2023).

[9]Joseph E. Lambson et al, *Administration Errors of Compounded Semaglutide Reported to a Poison Control Center—Case Series*, 63 J. Am. Pharmacists Assc'n 5 (2023), available at https://www.japha.org/article/S1544

48. FDA has issued guidance on its "Concerns with Unapproved GLP-1 Drugs Used for Weight Loss," which provides that: (1) "compounded drugs are not FDA-approved"; (2) use of compounded drugs containing "semaglutide" "can be risky for patients, as unapproved versions do not undergo FDA's review for safety, effectiveness and quality"; and (3) "FDA has received reports of adverse events related to compounded versions of semaglutide . . . . However, federal law does not require state-licensed pharmacies that are not outsourcing facilities to submit adverse events to FDA so it is likely that adverse events from compounded versions of these drugs are underreported."[10]

DEFENDANT'S UNLAWFUL MARKETING IN CONNECTION WITH ITS SALE OF UNAPPROVED COMPOUNDED DRUGS

49. Despite the foregoing, and well after NNAS's first use and registration of its Ozempic®, Wegovy®, and Rybelsus® marks, Defendant has used Novo Nordisk's Wegovy® trademark to market and sell Unapproved Compounded Drugs purporting to contain "semaglutide" that are not the Ozempic®, Wegovy®, nor Rybelsus® medicines, and has made false and misleading representations to patients regarding the nature of its Unapproved Compounded Drugs.

50. Defendant promotes its Unapproved Compounded Drugs by advertising a "medical weight loss" program, including on its website and social media pages.

51. Defendant falsely advertises its Unapproved Compounded Drugs by making statements that describe the Ozempic®, Wegovy®, and Rybelsus® medicines but that are false or misleading when in reference to Defendant's Unapproved Compounded Drugs.

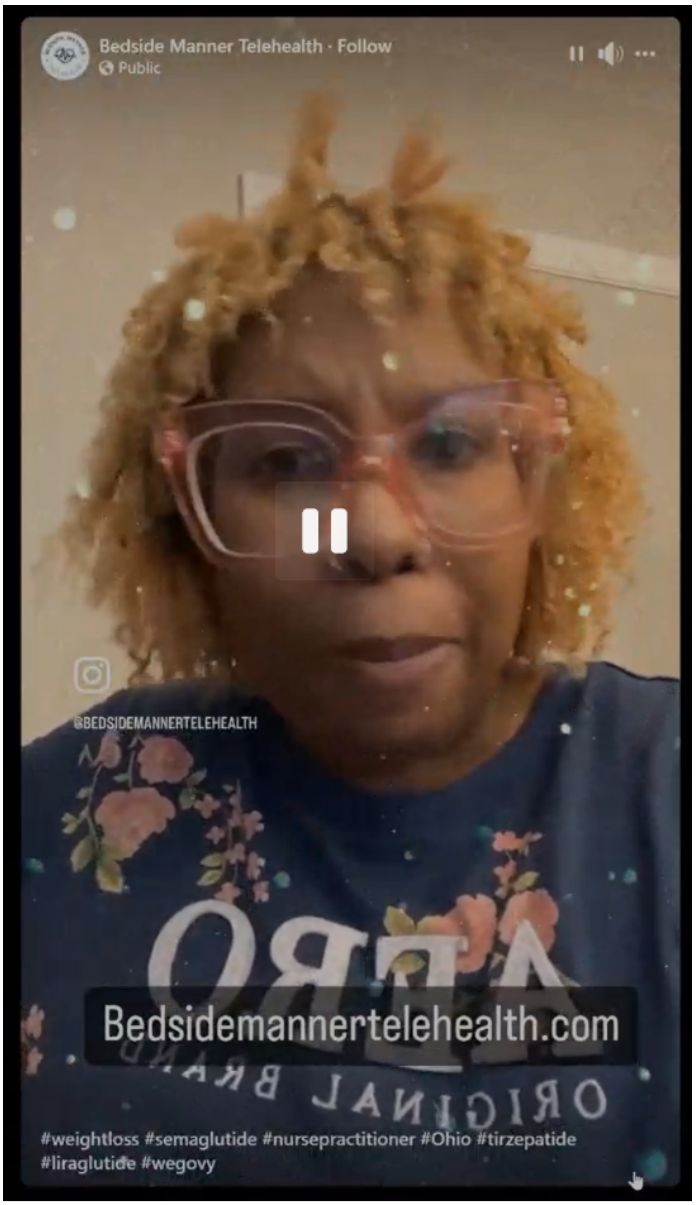
3191(23)00231-5/abstract (last visited November 7, 2024).

[10] FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss (last updated October 10, 2024).

52. Defendant has claimed or implied that its Unapproved Compounded Drugs have been approved by the FDA or have been reviewed by the FDA for safety, effectiveness, and quality:

53. Contrary to Defendant's representations, the FDA has made no such approval for a "semaglutide" peptide generally. Instead, the FDA has approved three of Novo Nordisk's complete medicines, which contain semaglutide for the specific indications outlined in the preceding paragraphs.

54. Defendant has used a #Wegovy hashtag to promote its Unapproved Compounded Drugs:



55. Defendant's use of this hashtag is likely to mislead customers into believing that they are purchasing legitimate Novo Nordisk medicines.

56. Defendant's misleading use of the Wegovy® mark is likely to cause patients to believe falsely that they are purchasing genuine Wegovy® medicine; that Defendant is a source for Novo Nordisk's FDA-approved semaglutide medicines; and that Defendant's services are provided, licensed, sponsored, authorized, or approved by Novo Nordisk.

57. On information and belief, Defendant has engaged in these unlawful practices to attract customers and generate revenues and profits.

58. Defendant's use of the Wegovy® mark is without the permission, consent or authorization of Novo Nordisk. Defendant has no right to use, and Defendant knows that it has no right to use, the Wegovy® mark in connection with Defendant's Unapproved Compounded Drugs or otherwise.

59. Novo Nordisk has no control over the nature, quality, or efficacy of the products sold by Defendant, including the Unapproved Compounded Drugs.

60. There is no need for Defendant to use the Wegovy® trademark to advertise or promote its Unapproved Compounded Drugs purporting to contain "semaglutide," other than to trade on the reputation of Plaintiffs and to create confusion in the marketplace or mislead the public regarding the origin, identity, or source of Defendant's Unapproved Compounded Drugs.

61. Defendant's unauthorized use of the Wegovy® trademark is likely to cause confusion, mistake, and deception and infringes on Plaintiffs' established exclusive right in the Wegovy® trademark.

62. Defendant's false and misleading statements and practices are likely to cause mistake and deception in the marketplace.

63. Defendant's false and misleading marketing is also likely to expose patients to unnecessary risks. Patients who mistakenly believe Defendant to be offering Novo Nordisk's FDA-approved medicines, or equivalent thereto, are unlikely to understand the unique risks associated with, or the lack of clinical trials or testing establishing the safety and effectiveness of, Defendant's Unapproved Compounded Drugs.[11]

[11]*See, e.g.*, Dozens Say They Lost Eyesight After Routine Surgery Using Compounded Pharmacy Drugs, WFAA, https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (last updated

64. On information and belief, unless enjoined by this Court, Defendant will continue to use the Wegovy® mark and otherwise falsely advertise its products as associated with or being the Wegovy® medicines, all in violation of Plaintiffs' rights.

FIRST CAUSE OF ACTION
Trademark Infringement in Violation of 15 U.S.C. § 1114(1)

65. Plaintiff NNAS realleges and incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

66. Plaintiff NNAS's Wegovy® marks are inherently distinctive, strong, valid, and protectable trademarks owned by Plaintiff NNAS.

67. Plaintiff NNAS's trademark registrations for its Wegovy® marks constitute *prima facie* evidence of the validity of the marks, of Plaintiff NNAS's registration and ownership of the marks, and of Plaintiff NNAS's exclusive right to use the mark in commerce on or in connection with the goods identified in the registrations.

68. By virtue of its prior use and registration, Plaintiff NNAS has priority over Defendant with respect to the use of the Wegovy® marks for pharmaceutical preparations sold in the United States.

69. Defendant uses one of the Wegovy® marks in connection with the sale, advertising, and promotion of Unapproved Compounded Drugs purporting to contain semaglutide.

70. Defendant's use in commerce of the Wegovy® mark is likely to cause confusion, to cause mistake, or to deceive with respect to Plaintiff NNAS's identical marks.

Feb. 13, 2019) (reporting mistaken belief of patient taking a compounded drug that "every pill you take, every shot you take is tested."); FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded?utm_medium=email&utm_source=govdelivery (last updated July 26, 2024) ("Compounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness.").

71. The above-described acts of Defendant constitute infringement of registered trademarks in violation of Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1), entitling Plaintiff NNAS to relief.

72. Defendant has unfairly profited from its trademark infringement.

73. By reason of Defendant's acts of trademark infringement Plaintiff NNAS has suffered damage to the goodwill associated with its marks.

74. Defendant's acts of trademark infringement have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiff NNAS, its federally registered trademarks and the valuable goodwill associated with those trademarks.

75. Defendant's acts of trademark infringement have irreparably harmed, and if not enjoined, will continue to irreparably harm the interests of the public in being free from confusion, mistake, and deception.

76. By reason of Defendant's acts, Plaintiff NNAS's remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiff NNAS is entitled to entry of preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

77. By reason of Defendant's willful acts of trademark infringement, Plaintiff NNAS is entitled to disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

78. This is an exceptional case, making Plaintiff NNAS eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

SECOND CAUSE OF ACTION
Trademark Infringement, False Designation of Origin, and Unfair Competition in Violation of 15 U.S.C. § 1125(a)(1)(A)

79. Plaintiffs reallege and incorporate by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

80. Defendant uses the one of the Wegovy® marks in commerce in connection with Defendant's goods and services and in commercial advertising and promotion of its goods and services.

81. Defendant uses the Wegovy® mark in commerce in a manner that is likely to cause confusion, or to cause mistake, or to deceive the relevant public into believing that Defendant's goods or services are authorized, sponsored, approved by, or otherwise affiliated with Plaintiffs, with Plaintiffs' genuine Wegovy® medicines, and with the Wegovy® marks.

82. The above-described acts of Defendant constitute infringement of the Wegovy® marks and use of false designations of origin in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A), entitling Plaintiffs to relief.

83. Defendant has unfairly profited from the actions alleged.

84. By reason of the above-described acts of Defendant, Plaintiffs have suffered damage to the goodwill associated with the Wegovy® trademarks.

85. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs, the Wegovy® trademarks, and the valuable goodwill associated with the trademarks.

86. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

87. By reason of Defendant's acts, Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

88. Because the above-described acts of Defendant are willful, Plaintiffs are entitled to disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

89. This is an exceptional case, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

THIRD CAUSE OF ACTION
Defendant's False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)

90. Plaintiffs reallege and incorporate by reference each the allegation in the preceding paragraphs of this Complaint as though fully set forth here.

91. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

92. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and qualities of Defendant's business practices and products, as set forth above.

93. Defendant has also engaged in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or

whom Defendant is trying to persuade to purchase its drugs) information that makes several false or misleading statements, including those described herein and in the exhibits hereto.

94. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

95. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

96. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

97. By reason of Defendant's acts as alleged above, Plaintiffs have suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation. However, Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant. Accordingly, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

98. Because the above-described acts of Defendant are willful, Plaintiffs are entitled to disgorgement of defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

99. This is an exceptional case, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

FOURTH CAUSE OF ACTION
Unfair Competition in Violation of Ohio Common Law

100. Plaintiffs reallege and incorporate by reference each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

101. The above-described acts of Defendant constitute common law unfair competition.

102. The above-described acts of Defendant unfairly and wrongfully exploit Plaintiffs' trademark, goodwill, and reputation.

103. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

104. By reason of Defendant's acts, Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, the Court should enter preliminary and injunctive relief, in addition to awarding disgorgement of Defendant's profits (enhanced at the Court's discretion) and corrective advertising costs to NNAS.

FIFTH CAUSE OF ACTION
Deceptive Trade Practices in Violation of Ohio R.C. 4165.01 et seq.

105. Plaintiffs reallege and incorporate by reference each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

106. The above-described acts of Defendant constitute deceptive trade practices in violation of the laws of the State of Ohio.

107. Specifically, said acts are likely to cause confusion as to source, sponsorship, approval, or certification of goods or services in violation of R.C. 4165.02(A)(2) and are likely to mislead consumers as to the standard, quality, or grade of Defendant's products in violation of R.C. 4165.02(A)(9).

108. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

109. By reason of Defendant's willful acts, Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, the Court should enter preliminary and permanent injunctive relief, in addition to awarding damages and attorney's fees.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request judgment against Defendant as follows:

1. That the Court enter a judgment against Defendant that Defendant has:

   a. Infringed the rights of Plaintiff NNAS in its federally registered Wegovy® mark, in violation of 15 U.S.C. § 1114(1);

   b. Infringed the rights of Plaintiffs in the Wegovy® mark and engaged in unfair competition, in violation of 15 U.S.C. § 1125(a);

   c. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);

   d. Engaged in unfair competition under the common law of Ohio and the Ohio's deceptive trade practices laws.

2. That each of the above acts was willful.

3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:

   a. using the Wegovy®, Ozempic®, and Rybelsus® marks in any unlawful manner, including but not limited to (i) use in any manner that is likely to cause confusion or mistake, to deceive, or otherwise infringe Novo Nordisk's rights in the Ozempic®, Rybelsus®, and Wegovy® marks in any way, or (ii) use in connection with the advertising, marketing, sale, or promotion of any Unapproved Compounded Drugs; and,

b. advertising, stating, or suggesting that any Unapproved Compounded Drugs, including but not limited to any Unapproved Compounded Drugs that either are available, directly or indirectly, from or through Defendant or the use of which or access to which is facilitated by, or with the involvement of, Defendant:

   i. are, or contain, genuine or authentic Novo Nordisk Novo Nordisk Ozempic®, Rybelsus®, or Wegovy® medicines;

   ii. are sponsored by or associated with Novo Nordisk;

   iii. are approved by the FDA; have been reviewed by the FDA for safety, effectiveness, or quality; or have been demonstrated to the FDA to be safe or effective for their intended use;

   iv. achieve or have been shown or proven to achieve certain therapeutic results, effects, or outcomes, including but not limited to by relying on or making reference to clinical trial results for Novo Nordisk's medicines;

   v. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes similar or identical to Novo Nordisk's medicines or are interchangeable with or equivalent to genuine Novo Nordisk medicines;

   vi. are associated or connected in any way with Novo Nordisk or Novo Nordisk's medicines; or

   vii. contain any ingredient (including but not limited to semaglutide) that is supplied by Novo Nordisk, is approved by the FDA, or is the same as any ingredient in any Novo Nordisk medicine.

c. engaging in any unfair and deceptive trade practices; and

d. engaging in any deceptive acts or practices.

4. That the Court require Defendant to disclose conspicuously and prominently in any public-facing materials for any Unapproved Compounded Drugs, including but not limited to all advertising, marketing, and promotional materials, that: (a) the Unapproved Compounded Drugs are compounded drugs that have not been approved by the FDA; have not been reviewed by the FDA for safety, effectiveness, or quality; and have not been demonstrated to the FDA to be safe or effective for their intended use; (b) the processes by which the compounded drugs are manufactured have not been reviewed by the FDA; and (c) FDA-approved medicines containing semaglutide are available.

5. That Plaintiffs be awarded monetary relief in the form of disgorgement of Defendant's profits for Defendant's false advertising and unfair and deceptive trade practices and that this monetary relief be trebled due to Defendant's willfulness, in accordance with 15 U.S.C. § 1117 and any applicable state laws.

6. That the Court award disgorgement of Defendant's profits resulting from Defendant's unfair and deceptive trade practices to Plaintiffs.

7. That Defendant be ordered to account for and disgorge to Plaintiffs all amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful actions.

8. That Plaintiffs be awarded punitive damages by reason of Defendant's willful unlawful actions.

9. For pre-judgment and post-judgment interest on all damages.

10. That the Court award Plaintiffs their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117 and any other applicable provision of law.

11. That the Court award Plaintiffs the costs of suit incurred herein.

12. For such other or further relief as the Court may deem just and proper.

November 8, 2024

Respectfully submitted,

/s/ Gregory J. Krabacher
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